

Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

Submission date 16/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.facit.net/facit_versie/explorer/groot/inhoud/algemeen.html

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT00110604

Secondary identifying numbers

NTR23

Study information

Scientific Title

Folic Acid and Carotid Intima-media Thickness: a 3-year randomised controlled trial (RCT) examining the effects of folic acid supplementation on vascular disease

Acronym

FACIT

Study objectives

To determine if folic acid supplementation can slow down atherosclerotic progression, age-related cognitive decline and age-related hearing loss.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Vascular disease

Interventions

Three-year long daily (oral) supplementation with 0.8 mg folic acid versus placebo pill.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Folic acid

Primary outcome measure

1. Change in mean carotid intima-media thickness
2. Change in maximum carotid intima-media thickness

Secondary outcome measures

1. Change in carotid distension
2. Change in hearing levels (pure tone air conduction averages of 0.5, 1, and 2 kHz & 4, 6 and 8 kHz)
3. Cognitive performance at year three (cognitive domains: simple speed, cognitive flexibility, and memory; and information processing speed and semantic memory)
4. Inflammatory markers and haemostasis markers

Overall study start date

01/09/1999

Completion date

01/12/2004

Eligibility

Key inclusion criteria

1. 50 - 70 years old
2. Men and post-menopausal women
3. Vitamin B12 greater than or equal to 200 pmol/l
4. Homocysteine greater than or equal to 13 umol/l

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

819

Key exclusion criteria

1. Current use of vitamin supplements containing B vitamins
2. Hormone replacement therapy or lipid-lowering therapy

Date of first enrolment

01/09/1999

Date of final enrolment

01/12/2004

Locations

Countries of recruitment

Netherlands

Study participating centre**Division of Human Nutrition**

Wageningen

Netherlands

6700 EV

Sponsor information

Organisation

Wageningen Centre for Food Sciences (WCFS) (The Netherlands)

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Sponsor type

Research organisation

Website

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Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Wageningen Centre for Food Sciences (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/01/2007		Yes	No
Results article		20/01/2007		Yes	No
Results article		01/05/2011	23/05/2022	Yes	No
Results article		01/06/2011	23/05/2022	Yes	No
Results article	post hoc analysis	06/04/2021	23/05/2022	Yes	No